

K131123

7. Summary of Safety and Effectiveness

JUL 5 2013

"510(K) SUMMARY"

Submitted By/

Contact Person:

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Date Prepared: April 19, 2013

- 7.1 Trade/Proprietary Name: Clickfine AutoProtect Pen Needle
- 7.2 Common/Usual Name: Injection Pen Needle
- 7.3 Classification Name: Hypodermic single lumen needle
- 7.4 Classification: FDA has classified Hypodermic single lumen needles in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.
- Panel: 80 Procode: FMI
- 7.5 Purpose of Submission: To make an administrative change to revise the Indications for Use to be consistent with the BD AutoShield Pen Needle so that the needles can be marketed Over the Counter (OTC) for all compatible injection pens.
- 7.6 Substantial Equivalence: The Clickfine AutoProtect Pen Needle is substantially equivalent to the Clickfine AutoProtect Pen Needles (K110312) and the BD AutoShield Pen Needles (K060007).
- 7.7 Device Description
The Clickfine AutoProtect Pen Needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of prescribed fluids. Each needle is individually packaged in a sealed protective container with a peel tab. The pen needle is used by peeling back the peel tab and snapping the housing onto the threaded end of the pen-injector. The back end of the cannula punctures the septum of the drug reservoir in the pen-injector. The outer protective cap is then removed. When the injection is needed the needle is inserted into

the chosen site. While inserting the needle into the skin, the safety shield glides into the housing enabling the needle to penetrate the skin barrier and into the subcutaneous tissue. While the safety shield glides into the housing the safety mechanism will be activated. The pen-injector delivers the medicinal product through the needle.

After the injection, in order to remove the needle from the skin, the user moves the pen injector away from the skin. As the pen and needle is moved away from the skin, the safety shield glides back in its initial position, completely covering the needle, where it will remain locked. The safety shield is designed to automatically cover the needle (provide passive protection) to minimize the risk of accidental needle-stick injury. Once the Clickfine AutoProtect Pen Needle is in the locked mode, it can no longer be used. The red safety lock indicator tells the user that the safety lock has been activated. The needle is detached from the injection device and disposed of in accordance with local regulations. For each subsequent injection, another disposable needle must be used.

7.8 Intended Use

The intended use of the device has been modified to combine the Indications cleared for the Clickfine AutoProtect Pen Needle (K110312) with the wording in the predicate device BD AutoShield Pen Needle (K060007):

The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for injections of fluids, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

7.9 Technological Characteristics

The technological characteristics have not changed.

7.10 Performance and Safety Data

As this was an administrative change, no performance and safety data were required to be submitted in support of the change.

7.11 Conclusion

Ypsomed AG concludes based on the information presented that the product is substantially equivalent to the current products legally marketed in the USA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

Ypsomed AG
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Re: K131123

Trade/Device Name: Clickfine Autoprotect Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 19, 2013
Received: April 22, 2013

Dear Dr. Reinmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131123

Device Name: Clickfine AutoProtect Pen Needle

Indications For Use:

The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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